

WHAT IS CLAIMED:

1. A process for manufacturing an implantable heart valve comprising the steps of:
providing a collection of similarly sized leaflets;
5 applying a load to each leaflet;
observing the strain response in each leaflet caused by applying the load;
sorting the leaflets into subgroups based on their respective strain responses such
that the leaflets in each subgroup each have a strain response within a predetermined
range; and,
10 attaching only leaflets from a single subgroup to the heart valve such that when
fluid pressure is applied to the implantable heart valve the leaflets thereon will exhibit
similar strain response.

2. The process of claim 1, wherein the step of providing a collection includes
15 providing a collection of natural tissue leaflets.

3. The process of claim 2, further including the step of chemically fixing the leaflets
prior to testing.

20 4. The process of claim 2, wherein the step of providing a collection of natural tissue
leaflets includes providing a collection of bovine pericardium leaflets.

5. The process of claim 1, wherein the step of providing a collection of leaflets
includes providing a collection of extruded collagen leaflets.

25 6. The process of claim 1, wherein the step of applying a load comprises applying a
load sufficient to create an average stress in at least some of the leaflets within a generally linear,
high modulus region of a stress/strain curve of the leaflet material.

7. The process of claim 1, further including the step of applying a load for a predetermined number of times prior to observing the strain response.

8. The process of claim 7, wherein the predetermined number is at least three.

9. The process of claim 1, further including the steps of:
performing an intrinsic load test on the leaflets; and
sorting the leaflets based on the intrinsic load test results.

10. The process of claim 1, wherein the step of forming subgroups of leaflets having a strain response within a predetermined range comprises a measuring a deflection of each leaflet resulting from applying a load thereto, and forming a subgroup of leaflets each having a deflection within about 0.030 inches of the others.

11. A process for manufacturing an implantable heart valve having multiple leaflets, comprising the steps of:

mounting the leaflet in a framing assembly so that portions which are to be sutured in the valve are held stationary, wherein the leaflet defines a cusp edge and a coapted edge generally opposite the cusp edge, and the framing assembly includes an upper member and a lower member, the lower member having a recess for receiving at least the cusp edge of the leaflet, the upper member being shaped to mate over the recess, and the framing assembly defining a cavity circumscribed by the recess, the step of mounting including positioning the leaflet in the recess and piercing the leaflet cusp edge with needles extending between and supported from movement by the upper and lower members, to hold at least the cusp edge of the leaflet stationary;

applying a load to the leaflet in a location adapted to simulate a point at which an average load is applied in the valve;

sensing the resulting strain in the leaflet;

sorting the leaflets into subgroups based on their respective strain responses such that the leaflets in each subgroup have a strain response within a predetermined range; and,

attaching only leaflets from a single subgroup to the heart valve.

5

12. The process of claim 11, wherein the step of applying a load comprises applying a mechanical deflector to an upper surface of the leaflet over the cavity.

13. The process of claim 11, further including the step of recording the sensed strain.

10

14. The process of claim 13, further including applying a load at least twice before recording the sensed strain.

15. The process of claim 14, further including the step of performing a droop test on the leaflet by extending the leaflet over the end of a structure, and observing the resulting droop of the extended end of the leaflet.

16. The process of claim 15, further including testing a second leaflet and correlating the results of the droop tests and applied load tests for the two leaflets.

20

17. The process of claim 11, wherein the leaflet is made of a leaflet material, and the step of applying a load comprises applying a load sufficient to stress the leaflet within a generally linear high modulus region of a stress/strain curve of the leaflet material.

18. The process of claim 11, wherein the step of applying a load comprises applying a load sufficient to stress the leaflet between 300 and 600 kPa.

25

19. The process of claim 1, wherein the stent comprises a wireform defining alternating commissures and arcuate cusps, the cusp edge of each prosthetic leaflet being attached along a wireform cusp, wherein the commissure portions of the prosthetic leaflets

30

terminate in outwardly extending tabs that each attach to a wireform commissure, and wherein tabs from adjacent leaflets are attached together at each of the wireform commissures.

20. The process of claim 19, wherein the tabs from adjacent leaflets extend outward
5 between spaced wires of the wireform commissure, and wherein inserts are provided around which the adjacent leaflet tabs wrap and are secured, the inserts being size larger than the distance that the wires of the wireform commissure are spaced apart so as to maintain the leaflet tabs on the outside of the wireform commissure.